

REMARKS

Claim 1 has been amended to incorporate the recitations of claim 17 and based on the disclosure in, e.g., test examples 2 and 3 on pages 27 and 28 of the present application where it is stated that the bicyclic ring of the bicyclic tautomer of the compounds tested was opened in the pH 2 solvent such that more than 5 % of the compound converted into the monocyclic tautomer. Claims 2-5 and 17 have been canceled. The dependency of other claims has been amended in view of the foregoing cancellation of claims. Further, claims 20-26 are added based on, e.g., original claim 16 and page 22, lines 8-18 of the present application). Claims 27-28 are added based on page 25, lines 15-24 of the present application.

Entry of the above amendment is respectfully requested.

Objection to Claim 1

On page 3 of the Office Action, the Examiner has objected to claim 1 because of an informality.

In response, Applicants have made the grammatical change indicated by the Examiner. Accordingly, withdrawal of this objection is respectfully requested.

Anticipation Rejection over Ueno '174

On page 3 of the Office Action, claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Ueno et al. (U.S. Pat. No. 6,583,174).

In response, Applicant submits that there is no disclosure of an enteric coating or enteric materials that may be compounded into the capsule base, either in the particular disclosure cited by the Examiner or elsewhere in the patent. Rather, Ueno '174 only generally discloses coatings and capsulating agents at col. 22, line 31, and Applicant submits that such a general disclosure does not teach or suggest the enteric requirement of the present invention in particular.

Thus, Applicant submits that the present invention is not anticipated by Ueno '174, and withdrawal of this rejection is respectfully requested.

Anticipation Rejection over Ueno '651

On page 4 of the Office Action, claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Ueno et al. (EP 0979651).

In response, Applicant notes initially that this rejection is improper because Ueno '651 is not 35 U.S.C. 102(e) prior art, since it is not a U.S. patent, a U.S. published patent application, or a WO publication that designated the U.S. and was published in English. Accordingly, this 35 U.S.C. 102(e) rejection should be withdrawn.

Further, Applicant notes that while Ueno '651 generally discloses an enteric-coated preparation at page 6, line 29, it does not teach or suggest particular coatings such as those set forth in the disclosure beginning at page 22, line 11 in the present application.

In addition, Applicant notes that Ueno '651 describes "Tablets or pills may be gastric or enteric-coated preparation" (see [0060] of Ueno '651).

However, Applicant submits that Ueno '651 does not describe or suggest that nausea in the subject is effectively prevented by administering the specific bicyclic compound as an enteric coated formulation to a subject, and the bicyclic tautomer is well protected even under an acidic condition by providing said compound with an enteric coating (see page 20, lines 4-16 of the present application). In addition, Ueno '651 does not describe or suggest which is a more suitable formulation for the bicyclic compound, a formulation resolved in the stomach or a formulation resolved in the intestine. Ueno '651 only describes a general formulation.

On the other hand, the present inventor found that more than 5% of the bicyclic tautomer is converted into the corresponding monocyclic tautomer under the condition of pH 2, and based on the findings, the inventor made the enteric coated composition of the present invention comprising the bicyclic compound, which is prevented from converting into its monocyclic tautomer in the stomach under the condition of pH 2 so that the bicyclic compound can be delivered to the intestine and act locally in the intestine.

Applicant submits that there is no information in cited reference to motivate a person skilled in the art to formulate the compounds recited in amended claim 1 such that the bicyclic compound is prevented from converting into its monocyclic tautomer in the stomach by covering with an enteric coating and to use the combination of the particular prostaglandin compounds recited in amended claim 1 and an enteric coating. Applicant submits that such combination is neither taught nor suggested by Ueno '651.

Thus, Applicant submits that a person skilled in the art would not have reasonably arrived at the present invention when considering Ueno '651, and withdrawal of this anticipation rejection is respectfully requested.

Anticipation Rejection over Ueno '912

On page 5 of the Office Action, claims 1-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Ueno et al. (WO 03/030912).

In response, Applicant notes initially that the enteric disclosure in Ueno '912 is similar to that set forth in Ueno '651 discussed above (i.e., a general disclosure of an enteric-coated preparation).

Thus, Applicant notes that Ueno '912 describes "Tablets and pills may be coated with an enteric or gastroenteric film, if necessary" (see page 25 lines 12-13 of Ueno '912).

However, Applicant submits that Ueno '912 does not describe or suggest that nausea in the subject is effectively prevented by administering the specific bicyclic compound as an enteric coated formulation to a subject, and the bicyclic tautomer is well protected even under an acidic condition by providing said compound with an enteric coating (see page 20 lines 4-16 of the present application). In addition, Ueno '912 does not describe or suggest which is a more suitable formulation for the bicyclic compound, a formulation resolved in the stomach or a formulation resolved in the intestine. Ueno '912 only describes a general formulation.

On the other hand, as discussed above, the present inventor found that more than 5% of the bicyclic tautomer is converted into the corresponding monocyclic tautomer under the condition of pH 2, and based on the findings, the inventor made the enteric coated composition of the present invention comprising the bicyclic compound, which is prevented from converting into its monocyclic tautomer in the stomach under the condition of pH 2 so that the bicyclic compound can be delivered to the intestine and act locally in the intestine.

Applicant submits that there is no information in the cited reference to motivate a person skilled in the art to formulate the compounds recited in amended claim 1 such that the bicyclic compound is prevented from converting into its monocyclic tautomer in the stomach by covering with an enteric coating and to use the combination of the particular prostaglandin compounds recited in amended claim 1 and an enteric coating. Applicant submits that such combination is neither taught nor suggested by Ueno '912.

Further, Applicant notes that while Ueno '912 generally discloses an enteric-coated preparation at page 25, lines 12-13, it does not teach or suggest particular coatings such as those set forth in the disclosure beginning at page 22, line 11 in the present application.

Thus, Applicant submits that a person skilled in the art would not have reasonably arrived at the present invention when considering Ueno '912, and withdrawal of this anticipation rejection is respectfully requested.

Obviousness Rejection over Ueno '174

On page 6 of the Office Action, claims 5-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueno et al. (U.S. Pat. No. 6,583,174).

In response, Applicant submits that as discussed above, there is not disclosure of an enteric coating or enteric materials that may be compounded into the capsule base, either in the particular disclosure cited by the Examiner or elsewhere in the patent. Further, Applicant submits that the general disclosure in Ueno '174 of coatings and capsulating agents at col. 22, line 31 does not teach or suggest the enteric requirement of the present invention in particular.

Thus, Applicant submits that the present invention is not obvious over Ueno '174, and withdrawal of this rejection is respectfully requested.

Obviousness Rejection over Ueno '651

On page 7 of the Office Action, claims 5-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueno et al. (EP 0979651).

In response, Applicant notes initially that Ueno '651 describes "Tablets or pills may be gastric or enteric-coated preparation" (see [0060] of Ueno '651).

However, as set forth above, Applicant submits that Ueno '651 does not describe or suggest that nausea in the subject is effectively prevented by administering the specific bicyclic compound as an enteric coated formulation to a subject, and the bicyclic tautomer is well protected even under an acidic condition by providing said compound with an enteric coating

(see page 20, lines 4-16 of the present application). In addition, Ueno '651 does not describe or suggest which is a more suitable formulation for the bicyclic compound, a formulation resolved in the stomach or a formulation resolved in the intestine. Ueno '651 only describes a general formulation.

On the other hand, the present inventor found that more than 5% of the bicyclic tautomer is converted into the corresponding monocyclic tautomer under the condition of pH 2, and based on the findings, the inventor made the enteric coated composition of the present invention comprising the bicyclic compound, which is prevented from converting into its monocyclic tautomer in the stomach under the condition of pH 2 so that the bicyclic compound can be delivered to the intestine and act locally in the intestine.

Applicant submits that there is no information in cited reference to motivate a person skilled in the art to formulate the compounds recited in amended claim 1 such that the bicyclic compound is prevented from converting into its monocyclic tautomer in the stomach by covering with an enteric coating and to use the combination of the particular prostaglandin compounds recited in amended claim 1 and an enteric coating. Applicant submits that such combination is neither taught nor suggested by Ueno '651.

Further, Applicant notes that while Ueno '651 generally discloses an enteric-coated preparation at page 6, line 29, it does not teach or suggest particular coatings such as those set forth in the disclosure beginning at page 22, line 11 in the present application.

Thus, Applicant submits that a person skilled in the art would not have reasonably arrived at the present invention when considering Ueno '651, and withdrawal of this obviousness rejection is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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